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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/299,139 04/23/99 BROWNING

J A013

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HM12/1023

BANSAL, G	
ART UNIT	PAPER NUMBER

BIOGEN INC.  
KERRY A FLYNN ESQ  
14 CAMBRIDGE CENTER  
CAMBRIDGE MA 02142

1642  
DATE MAILED:

10/23/01

*18*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.	09/299,139	Applicant(s)	Browning et al
Examiner	Gretta Bansal	Group Art Unit	1642
_____ _____ _____			

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on 8/6/01
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 17,18, 36-50, 51-94 is/are pending in the application.
- Of the above claim(s) 17,18, 36-50 is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 51-94 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

Art Unit: 1642

### **DETAILED ACTION**

1. The Group Art Unit location and the examiner of the application has been changed. This case has now been transferred as of 10/12/00. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Geetha P. Bansal, Group Art Unit 1642.

2. Applicant's amendment filed August 6, 2001 (Paper No: 10/C)) are acknowledged. Accordingly, claims 1-16, 19-35 have been canceled without prejudice, and claims 51-94 have been added.

Amendments to the specification have not been entered as the indication of line numbers are not clear - as to where the amendments and in what manner they should be made. Clarification is requested.

#### ***Response to Arguments***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Some of the rejections below were discussed by telephonic interview on 10/19/00 with the inventor, Dr. Jeffrey Browning and attorney, MS. Nicki Cox. It was decided to have a written rejection mailed, so Applicant had time to formulate amendments to claims that would render the claims allowable.

#### ***Claim Rejections - 35 USC § 112***

5. Claims 51-56, 58- 70, 84-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- A. Claims 51, 61, 65, 84, 91, 94 are indefinite in the recitation of “altering” as it is not clear what the metes and bound are, and whether the administration of the same antibodies can upregulate and downregulate the immune response and/or association of the immune complexes and B cell follicles.
- B. Claims 84, 91 and 94 are ambiguous in that it is not clear what sort of “association” of immune complexes and B cell follicles are altered and in what way.
- C. Claim 51 and 61 are unclear if “altering the immune response” is the same as or related to the phrase “therapeutically effective”. It is generally understood that “therapeutic” refers to some form of beneficial treatment, and it is not clear in the claim how the therapeutically effective is connected to the preamble of “altering the IR”.

6. Claims 51-56, 58-70, 84-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of immune responses as determined by the decrease in Ig levels, does not reasonably provide enablement for “altering” responses wherein the altering may be an increase in the immune response as measured by several other parameters including specific cytokine production, cellular immune responses and maybe the type and quality of immune responses of a certain type. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses composition and methods for treating immune disorders by inhibiting Lt $\beta$ R signalling using Lt $\beta$ R blocking agents, and specifically discloses an inhibition of antibody production. There is no guidance in the specification as to other means of altering the immune response, nor determining the association of immune complexes with B cell follicles. As set out in the rejection under 35 U.S.C., 2nd paragraph since the specification is not very clear with respect to the physical association of immune complexes with B cell follicles, nor other types of immune responses as measured by various art known methods of measuring immune response other than antibody responses, one of

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skill in the art would be forced into undue experimentation to practise the claimed invention as claimed.

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Fridays and alternate Wednesdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 3995.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 18, 2001



GEETHA P. BANSAL  
PRIMARY EXAMINER